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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,268	11/20/2003	Robert A. Ganz	1753.001US1	8160

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EXAMINER

DRYDEN, MATTHEW DUTTON

ART UNIT PAPER NUMBER

3736

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/718,268	Applicant(s) GANZ ET AL.	
	Examiner Matthew D. Dryden	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/01/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kenigsberg (4168703).

Regarding claim 1, Kenigsberg discloses a gastroesophageal reflux diagnostic tool comprising:

a catheter for insertion into a stomach for introducing a fluid into the stomach through the catheter, see around element 14 in Figure 3, and see Column 6, lines 5-31, wherein air is a liquid that can be used to monitor pressure,

a pressure measurement device associated with the catheter to sense a pressure in the stomach (see Column 4, lines 52-54) that is capable of determining a gastric yield pressure.

Regarding claim 8, see Column 4, lines 54-57.

Regarding claim 10,

a catheter for insertion into a stomach for introducing a fluid into the stomach through the catheter, see around element 14 in Figure 3, and see Column 6, lines 5-31, wherein air is a liquid that can be used to monitor pressure,

a pressure measurement device associated with the catheter to sense a pressure in the stomach (see Column 4, lines 52-54),

a monitor coupled to the measurement device capable of revealing a gastric yield pressure, Column 4 lines 50-51, wherein all of the pressures recorded would be shown on the chart and is capable of revealing a gastric yield pressure.

Regarding claim 11, see Column 4, lines 54-57.

Regarding claim 12, Kenigsberg discloses a strain gauge associated with the chart recorder, which is essentially the same as a pressure gauge because the pressure of the system is being monitored (see Column 4, lines 38-51).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenigsberg in view of Griffin et al (4878898). Kenigsberg discloses the claimed invention except for the device comprising a pressure transducer at the distal end of the catheter. Griffin et al teaches a catheter for measuring pressure that includes a pressure transducer at the catheter's distal end for monitoring the position and the pressure at the distal end of the catheter (see Column 10, lines 12-53). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Kenigsberg with a pressure transducer at the distal end of the catheter, as taught by Griffin et al, to monitor the changes in the pressure at the distal end of the catheter for positioning purposes.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenigsberg in view of Ackerman et al (6723053). Kenigsberg discloses the claimed invention except for the pressure measurement device including a pressure transducer at a proximal end of the catheter for measuring pressure of the air in the catheter. Ackerman et al teaches it is known to provide a catheter with a pressure transducer located at the proximal end of the catheter for correctly positioning the pressure sensor device in the gastrointestinal tract (see Column 2, lines 50-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Kenigsberg with a pressure transducer located at a proximal end of the catheter, as taught by Ackerman et al, for correctly positioning the pressure sensor device in the gastrointestinal tract.

Claims 4-7, 9, 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenigsberg in view of Shaker (6773452). Kenigsberg discloses the claimed invention except for the catheter comprising a first lumen for introducing air into the stomach and a second lumen for pressure measurement in the stomach with a side port open to the stomach. Shaker teaches to use two different lumens for introducing air into the stomach by means of balloon (element 32 in Figure 8), and a separate lumen connected to pressure port (element 39 in Figure 8) so that the two lumens are not connected allowing for accurate measurement of pressure within the stomach, and to allow for air to be introduced into the balloon without affecting the readings (Columns 5-7, lines 25-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Kenigsberg with two separate lumens one for introducing air to the stomach and one for monitoring the pressure in the stomach the second lumen having a side port open to the stomach, as taught by Shaker, so that the two lumens are not connected allowing for accurate measurement of pressure within the stomach, and to allow for air to be introduced into the balloon without affecting the readings.

Regarding claim 5 and 15, Kenigsberg teaches two lumens with varying diameters, see Figure 2.

Regarding claim 7, the lumens of Kenigsberg are co-axial.

Regarding claim 9, Kenigsberg discloses the claimed invention except for the catheter comprising a water-perfused catheter having one or more sensor openings along an intermediate portion of the catheter and a pressure transducer. Shaker

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teaches it is known to provide a pressure monitoring system with a water-perfused catheter to sense pressure at a position as the outflow of the perfusate encounters resistance (see column 7, lines 8-25), this provides another way of monitoring the pressure of the stomach and yield pressure to compare with the determined air pressures. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Kenigsberg with a water-perfused catheter having one or more sensor openings along an intermediate portion of the catheter and a pressure transducer, as taught by Shaker, to sense pressure at a position as the outflow of the perfusate encounters resistance this provides another way of monitoring the pressure of the stomach and yield pressure to compare with the determined air pressures.

Regarding claim 16, Kenigsberg discloses the claimed invention except for the catheter including an endoscope. Shaker teaches it is known to provide a catheter pressure measuring system with an endoscope to assist in positioning and monitoring the location of the catheter (see Column 7, lines 59-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Kenigsberg with an endoscope, as taught by Shaker, to assist in positioning and monitoring the location of the catheter.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenigsberg in view of Kilcoyne et al (6689056). Kenigsberg discloses the claimed invention except for the pressure measurement device including a detachable pressure transducer attached to a wall of the stomach. Kilcoyne et al discloses a detachable

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implantable monitoring probe, which includes a pressure monitoring system, to allow for continuous monitoring of the pressure in the gastrointestinal tract (see columns 2-4, lines 66-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Kenigsberg with pressure measurement device including a detachable pressure transducer attached to a wall of the stomach, as taught by Kilcoyne et al, to allow for continuous monitoring of the pressure in the gastrointestinal tract.

Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenigsberg in view of Laufer et al (6663639). Kenigsberg discloses the claimed method except for determining a gastric yield pressure using a pressure measurement device. Laufer et al teaches to use a pressure measurement catheter in combination with a liquid infused into the stomach of a pig to determine the yield pressure, see Columns 18-19 lines 48-22, to determine an appropriate yield pressure based on the fluid infused into the stomach to help decrease the amount of gastric reflux. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Kenigsberg to include a step of determining a gastric yield pressure, as taught by Laufer et al, to determine an appropriate yield pressure based on the fluid infused into the stomach to help decrease the amount of gastric reflux.

Regarding claim 19, Kenigsberg discloses such a device see Column 4, lines 54-57.

Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenigsberg in view of Laufer et al as applied to claim 17 above, and further in view of Shaker. Kenigsberg discloses the claimed invention except for the catheter comprising a first lumen for introducing air into the stomach and a second lumen for pressure measurement in the stomach with a side port open to the stomach. Shaker teaches to use two different lumens for introducing air into the stomach by means of balloon (element 32 in Figure 8), and a separate lumen connected to pressure port (element 39 in Figure 8) so that the two lumens are not connected allowing for accurate measurement of pressure within the stomach, and to allow for air to be introduced into the balloon without affecting the readings (Columns 5-7, lines 25-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the method and device of Kenigsberg with two separate lumens one for introducing air to the stomach and one for monitoring the pressure in the stomach the second lumen having a side port open to the stomach, as taught by Shaker, so that the two lumens are not connected allowing for accurate measurement of pressure within the stomach, and to allow for air to be introduced into the balloon without affecting the readings.

Regarding claim 20, Kenigsberg discloses the claimed invention and method except for the catheter including an endoscope. Shaker teaches it is known to provide a catheter pressure measuring system with an endoscope to assist in positioning and monitoring the location of the catheter (see Column 7, lines 59-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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further modify the method of Kenigsberg with an endoscope, as taught by Shaker, to assist in positioning and monitoring the location of the catheter.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,997,546 Foster et al disclose a gastric balloon catheter with improved balloon orientation

U.S. Pat. No. 6,259,938 Zarychta et al disclose a monitoring catheter and method of using same

U.S. Pat. No. 5,108,364 Takezawa et al disclose a monitoring catheter for medical use.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD


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